UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION	MDL No. 15-2666 (JNE/FLN)
This Document Relates To: *All Cases*	

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Regulations

Plaintiffs submit this memorandum in opposition to Defendantsô Motion to Exclude Plaintiffsô Expert Dr. Yadin David.

INTRODUCTION

Dr. Yadin David is a world class biomedical engineer and risk manager who has spent his career evaluating medical devices and adverse events, consulting for medical device companies on the creation of new products, and advising employees of the U.S. Food & Drug Administration (FDA) on regulatory issues. Dr. Davidôs report contains his conclusions from ña hazard analysis which [he] was asked to perform with respect to the Bair Hugger patient warming system.ò[1] The scope of his report was ñto examine the potential hazard raised by the use of the Bair Hugger device in orthopedic implant surgeries.ò [2]

Dr. David concluded that ñafter a review of an extensive body of literature, documents, testimony, expert testing, as well as inspection of the device itself, it is [his] biomedical engineering opinion that the potential airborne contamination risk from the device is credible and supported by experimental and clinical evidence.ò[3] Moreover, Dr. David concluded that 3M ñfailed to follow common practices in the medical device manufacturing industry by failing to adequately investigate the issue of the Bair Huggerôs

[1] Ex. 1 (David Rpt.), 1. All references to Ex. __ are references to exhibits to the Declaration of Genevieve M. Zimmerman in Support of Plaintiffsô Response Opposing Defendantsô Motion to Exclude the Opinions and Testimony of Dr. Yadin David, filed concurrently herewith.
[2] *Id.*
[3] *Id.* at 8.

impact on orthopedic implant surgeries and adequately mitigate this hazard.ò[4] As such, Dr. David believes that 3M ñdid not act as a reasonably prudent medical device manufacturer would act in response to these issues.ò[5] Dr. David also concluded that 3M ñdid not provide adequate warnings and precautions about the potential for airborne contamination, despite its awareness of the likelihood of joint infection.ò[6] Finally, Dr. David concluded that ñthe Bair Hugger presents an unreasonable danger in orthopedic operating rooms.ò[7]

The bulk of 3Môs attacks on Dr. Davidôs opinions concern his qualifications, but 3Môs Motion badly misrepresents and underappreciates the nature of Dr. Davidôs credentials and background. As described more fully below, Dr. David possesses extensive qualifications to render opinions on federal regulations and their application to this case.[8] Additionally, Dr. David is qualified to evaluate a medical device for potential clinical risk. Finally, Dr. Davidôs background has provided him with expertise on the customary practices in the medical device industry.

3Môs remaining complaints purport to attack Dr. Davidôs methodology, but these complaints distort the record and ignore Dr. Davidôs testimony. Moreover, 3Môs criticisms tend to focus on which specific facts or data Dr. David did or did not rely upon. Such criticisms are appropriate for cross-examination, but they do not ultimately speak to

[4] *Id.* at 44.
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] Ex. 2 (Dr. Yadin David Curriculum Vitae).

the underlying methodology. In this case, Dr. David applied the same methodology which he uses outside litigation to evaluate the risk of medical devices,[9] and he gave the kind of opinions that have been endorsed by courts across the country that have examined his testimony. Defendantsô motion should be denied.

LEGAL STANDARD

ñThe purpose of the *Daubert* inquiry is always the same: ó[t]o make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.ôò *Hollander v. Sandoz Pharmaceuticals Corp*., 289 F.3d 1193, 1206 (10th Cir. 2002) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). ñHowever, the rules on expert testimony have a óliberal thrustô and generally relaxed the traditional barriers to ópinionô testimony.ò *Woodard v. Stryker Corp.*, 11-CV-36-F, 2012 WL 3475079, *3 (D. Wyo. July 16, 2012) (quoting *Beech Aircraft Corp. v. Rainey,* 488 U.S 153, 169 (1988)).

Scientific evidence is reliable if it is based on an assertion that is grounded in methods of science. *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579, 590 (1993). It is unreasonable to require the subject of scientific testimony to be ñknownò to a certainty, since science is an evolving process, and there are no certainties in science. *Id*. The Supreme Court has recognized that there is a range in which experts might reasonably differ on issues of science, and that such conflicting evidence should be

[9] Ex. 1 (David Rpt.), at 5-7.

admitted to aid the jury in deciding those issues. *Kumho Tire*, 526 U.S. at 153; *see also Johnson v. Mead Johnson & Co.,* 754 F.3d 557, 564 (8th Cir. 2014)(ñthe jury, not the trial court, should be the one to decide among the conflicting views of different experts.ò) (citing *Kumho Tire*, 526 U.S. at 153).

For these reasons, ñ[t]he exclusion of an expertôs opinion is proper only if it so fundamentally unsupported that it can offer no assistance to the jury.ò *Wood v. Minnesota Mining and Mfg. Co.*, 112 F.3d 306, 309 (8th Cir. 1997) (quoting *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (9th Cir. 1995)). In this case, Dr. Davidôs testimony, based upon decades of experience in device investigation and hazard analysis, far surpasses the minimum requirements for the admission of expert testimony.

ARGUMENT

I. If the Court Chooses to Admit Regulatory Matters, Dr. David is Qualified to Assist the Jury in Understanding the Regulatory Process.

Defendants have broadly moved for an order excluding ñDr. Davidôs regulatory opinionsò including his opinions as to ñDefendantsô 510(k) submissions.ò[10] Defendantsô Motion should be denied.

As many courts have found, any exploration into issues involving federal regulation and the FDA tend to require an inordinate expense of trial time while providing little probative value and massive potential prejudice. Given the circumstances of this case, Plaintiffs believe that admission of FDA testimony will be especially time consuming, confusing, and prejudicial. However, if the Court chooses to admit testimony

[10] Doc. 766, Def. Mem. 6-13.

relating to the FDA, Dr. David possesses extensive qualifications in regulatory matters that will assist the jury.

A. Testimony about the FDA will be time-consuming, confusing, and prejudicial.

Class II medical devices such as the Bair Hugger are not subjected to the FDAôs stringent premarket approval (PMA) process. Rather, these devices are granted clearance under the far less demanding requirements of 510(k). Scores of federal courts have recognized Supreme Court precedent holding that the 510(k) process is not relevant to a juryôs determination of a tort claim based on a product defect. These courts also recognize that even if the 510(k) process had any probative value, it would be far outweighed by prejudice and the potential for jury confusion.

ñThe 510(k) process is not a safety statute or administrative regulation.ò *Lewis v. Johnson & Johnson*, 991 F.Supp.2d 748, 755 (S.D.W.Va. 2014). ñSince the §510(k) process is focused on *equivalence,* not safety, substantial equivalence determinations provide little protection to the public.ò *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 471 (1996) (emphasis in original); *see also Riegel v. Medtronic, Inc*., 552 U.S. 312, 323 (2008) (ñ§510(k) is ófocused on *equivalence,* not safety.ôò). ñThe attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.ò *Medtronic, Inc*., 518 U.S. at 479 (*quoting* Adler, 43 Food Drug Cosm. L.J. at 516). ñThe FDA thus prohibits manufacturers of devices cleared through the 510(k) process from making any representations that their devices have been approved by the

FDA.ò *Lewis*, 991 F.Supp.2d at 755. For this reason, the 510(k) process is not relevant to a determination of the safety or effectiveness of a device in a tort action. *See, e.g., Cisson v. C.R. Bard, Inc*., 2013 WL 3821280, at *7 (S.D.W.Va. July 23, 2013) (ñThe FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own.ò); *see Bellew v. Ethicon, Inc*., 2014 WL 6674424, at *8 (S.D. W.Va. Nov. 24, 2014) (ñBound by Supreme Court precedent, I cannot conclude that 510(k) clearance speaks to the safety or effectiveness of the [device].ò).

The most thorough recent examination of this issue in the context of multidistrict device litigation came last year, when the Fourth Circuit spoke directly to the irrelevant and prejudicial nature of FDA testimony:

> [Defendantôs] evidence would have initiated a battle of experts: [Defendant] was prepared to characterize the review process as ñthoroughò and ñrobustò and the FDAôs clearance of the Avaulta Plus as ñan affirmative safety ... decisionò based on ñspecific safety and efficacy findings.ò [Plaintiff] was prepared to argue, as she has done before this Court, that these characterizations wildly inflate the significance of the process, and that in any event [Defendant] failed to make necessary disclosures to the FDA.
>
> All of this, the district court reasoned, presented ñthe very substantial dangers of misleading the jury and confusing the issues.ò The court expressed concern that subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a ñmini-trialò could easily inflate the perceived importance of compliance and distract the jury from the central question before it -- whether [defendantôs] design was unreasonable based on any dangers it posed versus the costs required to avoid them. While 510(k)

> clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific. The vast majority of courts have said so, and having been thoroughly briefed not only by the parties but by several amici, we say so again today.

In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair System Products Liability Litigation, 810 F.3d 913, 921ï 22 (4th Cir. 2016); *see also In re Fosamax Products Liability Litigation*, 2010 WL 4242708, at *2 (S.D.N.Y. 2010) (ñThe cases in this MDL are not governed by federal regulations but by state law theories of negligence and strict liability.ò).

Similarly, in the NexGen MDL, the court barred either sideôs experts from providing ña narrative description of the FDAôs processes for regulation of medical devices, its 510(k) process in general, an overview of artificial knee devices, and the history of Zimmerôs 510(k) submissions.ò *In re Zimmer NexGen Knee Implant Products Liability Litigation*, 2015 WL 5145546, at *10 (N.D.Ill. 2015). The court held that the 510(k) process was not relevant to ña deviceôs safety and effectiveness.ò *Id*. at *14. Moreover, the court in NexGen explained why Rule 403 required exclusion even assuming the testimony had some probative value:

> [A]ssuming any expert testimony on the 510(k) clearance process would have probative value at Ms. Battyôs trial (a matter not free from doubt), it is ñsubstantially outweighedò by the danger of misleading the jury. *See* Fed. R. Evid. 403. As the brief review of the differences between PMA review and 510(k) review outlined above suggests, there is significant risk that jurors may be led to believe that the 510(k) clearance that Zimmer's NexGen Flex system components received is equivalent to a finding of non-negligent design, which is an incorrect statement of law.

Id. at *14. The court concluded by stating that ñthe FDA's finding of substantial equivalence, as a matter of law, is not a safety determination, and simply has too little probative value on the issue of whether the NexGen Flex system was defective, and whether those defects injured [plaintiff].ò *Id.* at *15.

The court in the *Ethicon* MDL likewise ruled that experts could not testify about 510(k) or regulatory issues, recognizing ñthe risks of leading the jury into the confusing domain of the FDA.ò *Bellew v. Ethicon, Inc*., 2014 WL 6680356, at *10 (S.D. W.Va. Nov. 25, 2014). The court held that ñto the extent that [expertsô] opinions implicate the 510(k) clearance process in general or with respect to the [device] specifically, his opinion is improper and therefore EXCLUDED.ò *Id.* The court emphasized that it would ñnot tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process.ò *Id.*

In this particular case, admission of testimony relating to the FDA will consume an extraordinary and inordinate amount of time. The parties will be forced to dispute whether the device was improperly cleared, which will in turn require an exploration into the FDAôs decision-making process and over twenty years of regulatory interactions. The situation is complicated by the FDAôs highly unusual and irregular letter of August 30, 2017, in which the FDA appears to take a stance in this litigation, without having held hearings or otherwise specified in any what information the *sua sponte* proclamation is based upon. Ultimately, any testimony about the FDA or the 510(k) regulatory process presents enormous prejudice.

B. Dr. David is Qualified to Testify about FDA Regulations

Should this Court to decide to admit testimony regarding the FDA and 3Môs regulatory compliance or to Defendantsô initial 510(k) clearance, Dr. David possesses qualifications which allow to him to assist the jury in understanding these complex issues and their application to the case, notwithstanding Defendantsô arguments to the contrary.[11] Dr. David has an educational background in medical device regulation at the masters and doctorate level.[12] He has also authored a chapter for upcoming textbook regarding ñrisk processes of medical devices subject to regulation.ò[13] In his consulting work, he ñprovide[s] regulatory services to startup companies in the medical device field,ò including ñadvis[ing] them on how to be ready for 510(k) submission.ò[14]

Dr. David is the Chairman of the FDAôs Medical Device Good Manufacturing Practice Advisory Committee.[15] Dr. David also serves as a member of the FDAôs Orthopedics and Rehabilitation Medical Devices Advisory Panel, as well as the General Hospital and Personal Use Medical Devices Panel.[16] Dr. David also serves as Senior Biomedical Research Service Credentials Reviewer for the FDA.[17] In connection with his work for the FDA, Dr. David was awarded the FDA Commissionerôs Special Citation.[18]

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[11] Doc. 766 (3Môs Motion to Exclude Expert Testimony of Dr. David) at 7-8.
[12] Ex. 3 David Dep., (65:15-25).
[13] *Id.* at (67:1-3).
[14] *Id.* at (63:19 to 63:24).
[15] Ex. 1, (David Rpt.) at 3.
[16] Ex. 2, (David CV) p. 3
[17] *Id.* at at p. 2.
[18] *Id.* at p. 3.

As part of his work, Dr. David has been asked to review 510(k) applications for clearance on behalf of the FDA as part of his duties on the advisory panel.[19] For example, Dr. David has been asked to examine 510(k) applications ñto determine if the instructions for use are sufficiently covering the risk associated with the use.ò[20] He has also experience consulting in the FDAôs ñsubstantial equivalenceò decision-making process.[21] On other occasions, Dr. David has been asked to examine ñif the submitter identified sufficient risk that might be existing in the clinical environment when the device is in use.ò[22] Dr. David has also been asked to examine ñif there is sufficient content in the classification of the device to ensure safety when this device is deployed, or there is a need for special control to be added.ò[23] As Dr. David summarized:

> I have obtained education and training throughout my career and have been working as a consultant to the Food and Drug Administration on several panels and have been trained by the Food and Drug Administration to fulfill that role. And I recently have been asked to become a regulatory advisor to the Innovation Institute of the Texas Medical Center based on my experience and training.[24]

In *Woodard v. Stryker Corp*., a product liability litigation involving a pain pump manufactured by Stryker, the U.S. District Court for Wyoming held that Dr. David was qualified to ñtestify about federal regulations and Stryker's alleged breach of numerous

[19] Ex. 3, David Dep. (182:7-12).
[20] *Id.* at 184:8-11.
[21] *Id.* at (188:9-189:12).
[22] *Id.* at (185:6-8).
[23] *Id.* at (185:11-15).
[24] *Id.* at (64:20 to 65:9).

federal regulations to demonstrate that Stryker failed to act like a reasonably prudent manufacturer.ò *Woodard*, 2012 WL 3475079 at *7. The Court emphasized that Dr. David ñserved as a biomedical engineer for over thirty yearsò and was ñcertified in clinical engineering by the Healthcare Technology Commission.ò *Id.* In addition, the court noted that Dr. David advised ñmembers of the FDA staff about issues related to applications submitted for the 510(k) review process, device labeling and special controls.ò *Id.* And it further noted ñDr. David is familiar with the 510(k) process as well as other processes medical manufacturers must follow,ò and that he ñpreviously provided expertise and advice regarding 510(k) applications and participated in the preparation of 510(k) applications.ò *Id.* at *8ï 9. Thus, the *Woodward* court specifically rejected the contentions 3M asserts here:[25] that Dr. David ñnever worked for the FDAò and that he has not been involved in ñany FDA compliance decision.ò

In admitting Dr. Davidôs opinions, the court explained:

> After reviewing both expertsô reports, the Court finds that é Dr. David applied reliable methodology to reach their conclusions in this matter.é Dr. David explains the applicable standards of care, the applicable regulations that apply to establish the standards of care, and explains how Stryker allegedly violated these regulations. This is the same methodology employed by numerous regulatory experts in many cases, including Stryker's own expert. Thus, the Court finds that é Dr. David employed reliable methodology to reach their conclusions. Stryker's arguments go to the weight of the testimony, rather than its admissibility.

[25] Doc. 766 (3Môs Motion to Exclude Expert Testimony of Dr. David) at 9.

Id. at *10. The court noted that ñStryker spends significant effort in its brief discussing what Dr. David has not done. However, Stryker ignores the knowledge, skill, experience, training, and education actually possessed by Dr. David.ò *Id.* at *8. That is precisely the same argument 3M has made here.

3M argues to the contrary that ñ[a]t least one other court has recognized that Dr. David is not qualified to opinion on regulatory matters.ò [26] In that case, however, the court simply said that ñnothing in Davidôs report suggests that he is a regulatory expert.ò *Stevens v. Stryker Corp.,* 2013 WL 4758948, at *4 (W.D. Wis. Sept. 4, 2013). Thus, the problem was a deficient report, not a deficit of experience. As reflected his report and CV in this case and many others, Dr. David has an extensive regulatory background.

II. Dr. David is Qualified to Perform Hazard Analysis of Medical Devices.

3M wrongly complains (at 7) that Dr. David ñis not a clinicianò and therefore cannot review clinical materials and reach conclusions about risk.[27] That is simply false. ñDr. David is an eminently qualified biomedical engineer,ò *McLane v. Ethicon Endo–Surgery, Inc*., 2014 WL 12621192, at *2 (M.D.Fla. 2014), who sits as the Chairman of the Clinical Engineering Division of the International Federation of Medical and Biological Engineering (IFMBE) and has been awarded the Lifetime Achievement Award from the American College of Clinical Engineering (ACCE).[28] Dr. David also served as an advisor to the World Health Organization (WHO) on Health Infrastructure

[26] *Id*. at 8.
[27] Doc. 766 p. 7.
[28] Ex. 1 (David Rpt.) 3; Ex. 2, (David CV) 3.

and Technology, and he sits on the Editorial Board of the Journal of Health and Technology.[29] As Dr. David explained: ñI've been working in the biomedical devices field for four decades and use my expertise to understand how a device works safely and what risk is associated with them, seeing it from the clinical side.ò[30]

Expertise in biomedical engineering extends to ñhow a device should be designed and constructed, as well as the proper design and implementation of studies to determine the existence, nature and magnitude of potential risks and benefits associated with various device designs and the extent to which those risks and benefits are realized in clinical practice.ò *Taylor v. Danek Medical, Inc*., 1999 WL 310647, at *4 (E.D.Pa. 1999). This is exactly the expertise Dr. David applied in his report, as he described in deposition:

> In my work, Iôm expected to read clinical literature and scientific publications. I am educated, trained, and have the experience to understand the study structure and the strength of the conclusions. And in my evaluation of various medical devices, at the hospital I worked for over 25, 30 years, part of the process was to review current medical and scientific literature relating to device performance é that looked at overall what you asked earlier, benefit-to-risk ratios and understand what the product risk based on the information from the manufacturers, but also based on experience that comes from clinical studies that published in peer-reviewed journals.[31]

[29] *Id.*
[30] Ex. 3 David Dep. (65:20-25).
[31] *Id.* at (280:15-281:9).

Just as in prior cases, Dr. David has directly applied his decades of ñexperience in the risk-assessment of healthcare equipment.ò *Woodard*, 2012 WL 3475079 at *8. Understanding and applying clinical information and assessing clinical risk is a fundamental component of biomedical engineering. *See, e.g., In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 711 F.Supp.2d 1348, 1373 (M.D.Ga.2010) (admitting biomedical engineering testimony as to ñhow the design and construction of [the product] can cause the complications.ò). Indeed, FDA regulations recognize that biomedical engineers are qualified to assess the clinical risk of a medical device in adverse event investigations. Under the FDAôs medical device adverse event reporting statute, manufacturers must report events that ñmay have caused or contributed to a death or serious injury.ò *See* 21 CFR 803.20. However, they are not required to report an event if the facts would ñlead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury.ò *Id.* Under the statute, ñ[p]ersons qualified to make a medical judgment includeé biomedical engineers.ò *Id.*

Moreover, Dr. David possesses far more relevant expertise than the typical biomedical engineer because he has extensive direct experience in the evaluation of medical devices for patient risk. For almost twenty years, Dr. David served as Director of Biomedical Engineering at the Texas Medical Center, where he oversaw medical devices for three hospital facilities ï Texas Childrenôs Hospital, St. Lukeôs Episcopal Hospital,

and the Texas Heart Institute.[32] 3M claims that Dr. David ñsat on a committee that evaluates medical devices,ò but this statement grossly underrepresents Dr. Davidôs accomplishments and responsibility. Dr. David was the creator of the groundbreaking ñMedical Technology Evaluation Committeeò at the Texas Medical Center, and he served as its director from 1989 to 2008.[33] As Dr. David explained:

> As part of my work in this capacity and other evaluative functions, I have examined products to support and facilitate the evaluation and deployment decisions of various types of medical technology. The selection process typically involved reviewing the product, understanding the environment of use and potential risks, researching the regulatory background, and considering the evidence gathered and the conclusions reached in peer-reviewed scientific publications.[34]

In the *Ethicon* litigation, the U.S. District Court for the Middle District of Florida discussed Dr. Davidôs extensive qualifications in risk management and adverse event investigations:

> The Court takes note of Dr. Davidôs experience in the selection process and servicing of health equipment; training of hospital staff in the safe use of medical equipment; his varied roles in developing and leading professional organizations; his extensive educational background; and over one hundred publications within the intersection of medicine and engineering, including those on risk management and adverse event investigations of medical products.

[32] Ex. 2, (David CV) 3.
[33] Ex. 1, (David Rpt.) 7; Ex. 3, David Dep. (280:15-281:9); Ex. 2, (David CV) 7.
[34] Ex. 1, David Rpt. 4.

McLane, 2014 WL 12621192, at *4. Similarly, in the District of Wyoming, the court found Dr. David qualified to opine on the risk of a medical device, and admitted his opinion that ñStryker manufactured and marketed a device that was unsafe and presented unreasonable biomedical engineering risk in connection with its use in intra articular space.ò *Woodard*, 2012 WL 3475079 at *9. The court in *Woodard* also admitted Dr. Davidôs opinion that Stryker ñfailed to warn potential end users about the risks resulting from use of this device.ò *Id.* Dr. David is likewise qualified to render similar opinions in this case.

III. Dr. David is Qualified to Opine on the Medical Device Industry Standard of Care.

3M wrongly contends that Dr. David ñis very much an *outsider* to the medical device industry.ò[35] This is a gross misstatement of Dr. Davidôs career, which includes extensive experience in the medical device industry. ñDr. David has, among many other things, served as an engineering consultant for start-up companies that bring new products to the market.ò *McLane*, 2014 WL 12621192, at *3. Dr. David also currently serves as Interim CEO for Canopy Edge, a medical device manufacturer of vascular catheters.[36] Dr. David also ñprovides professional services to manufacturers of medical devices that would like to start or improve their field biomedical services.ò[37] During his

[35] Doc. 766 at 16.
[36] Ex. 3, David Dep. (198:21-199:2).
[37] *Id.* at (63:9-12).

deposition, Dr. David described a number of these consulting services he has rendered to medical device manufacturers.[38]

Moreover, as noted above, Dr. David is the Chairman of the FDAôs Medical Device Good Manufacturing Practices Committee.[39] It is preposterous to think that the Chair of this committee would be unfamiliar with standards of care in medical device manufacturing practices. As stated by the court in *Woodard*, *"*based on his experience, he is familiar with the steps a reasonable device manufacturer should go through in its decision to manufacture and market a product.ò *Woodard,* 2012 WL 3475079 at *9. There, the court admitted Dr. Davidôs ñopinion regarding standard of care for a reasonable and prudent medical device manufacturer.ò *Id*. Much like here, Dr. David in that case ñexplain[ed] how reasonable manufacturers should act and explain[ed] his opinion regarding whether Stryker met the standard of care.ò *Id.* at *10. Similarly, the court in *McLane* wrote that:

> This Court recognizes Dr. Davidôs vast experience, training and education give him status as an expert in biomedical engineering. As a biomedical engineer he has learned principles relating to the design and safety of medical products, and applied those theories in his detailed evaluation of the engineering and marketing of the [device].

McLane, 2014 WL 12621192 at *4.

Finally, Dr. Davidôs explanation of corporate documents and events will be helpful to the jury to explain the basis for his various opinions about 3Môs breach of its

[38] *Id.* at (198:15-201:13).
[39] Ex. 2,David CV.

standard of care. Dr. David will not be providing a narrative or ñclosing argumentò as 3M suggests (at 10-12). Each of the documents cited by Dr. David contain highly technical information and events which explain how he concluded that 3M did not act as a reasonably prudent device manufacturer. Dr. David is permitted to use these documents, while explaining the ñcontext in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.ò *In re Fosamax Products Liability Litigation*, 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009).

3M also seeks to exclude testimony in which 3Môs claims that Dr. David speculates about the motives or state of mind of corporate decision-makers. 3M cites Dr. Davidôs opinion that the Defendants ñconsciously failed to meetò their obligations (David Rpt. at 44). 3M claims this statement is impermissible, but it relies on an overly expansive reading of an order from the *Baycol MDL*. In that case, the expert offered ñhis speculations that certain statements made by Bayer to the FDA likely played a role [in the case]ò as well as ñhis personal views on the ethical obligations of Bayer and other pharmaceutical companies.ò *In re Baycol Products Litigation*, 532 F.Supp.2d 1029, 1053 (D.Minn. 2007). Here it is simply Dr. Davidôs contention that 3M was in possession of information that it consciously ignored, and he relies on the content of 3M internal documents to support his opinion on this breach of the standard of care.[40] Experts such as Dr. David are ñallowed to testify as to the standard of care for pharmaceutical

[40] Ex. 1 (David Rpt.).

companies.ò *Id*. at 1054. Dr. David will not testify about 3Môs motives, but he will testify about what the Defendants knew and when they knew it.

IV. 3M's Complaints about Dr. David's Methodology are Inaccurate and Suited for Cross-Examination

3M raises a series of attacks on Dr. Davidôs methodology, but these complaints tend to distort the record and ignore Dr. Davidôs testimony. Moreover, the attacks tend to focus on which specific facts or data Dr. David did or did not rely upon. Such criticisms are appropriate for cross-examination but do not ultimately speak to the underlying methodology.

A. Dr. David considered published articles frequently touted by 3M.

3M claims that Dr. David ñignor[ed] scientific evidence that is contrary to his opinions.ò[41] Specifically, 3M claims there are a number of published studies that are favorable to the Bair Hugger, and that ñDr. Davidôs analysis does not address *any* of these articles.ò[42] This is simply false. Dr. Davidôs report includes a discussion of articles frequently cited by 3M in support of the Bair Hugger. He also discussed these studies in deposition.[43] In addition, Dr. David discussed how his materials included a ñreview article of existing literature by Wood, Moss and Keenan.ò[44] This article from The Journal

[41] Doc. 766 at 21.
[42] *Id.*
[43] *See, e.g.,* Ex. 3 David Dep. (304:23-305:12).
[44] *Id.* at (273:10-11).

of Hospital Infection[45] collected and analyzed the recognized body of published literature on the issue of forced air warming contamination, including the studies touted by 3M. Dr. David noted in his report that given the risk identified from Bair Hugger use, ñthe authors recommended that facilities consider the use of alternative warming technologies.ò[46] Finally, in addition to the deposition of company executives, clinical staff, and engineers, Dr. David has reviewed the testimony of 3Môs retained clinical consultant.[47] All of the peer reviewed studies have been discussed at length in these depositions.

3M pays special attention to a publication by Kurz *et al* in 1996 regarding the supposed benefits of normothermia in a colorectal surgery.[48] 3M criticizes Dr. David for not including the article in his literature review. However, Dr. David explained in his deposition that for the purposes of the risk he was to analyze, there was ñno correlation between colorectal procedures and orthopedic surgical procedures.ò[49] Moreover, Dr. David does not believe that warming should be denied to patients, only that warming be

[45] *See* Wood, Moss, Keenan, Reed, and Leaper, *Infection control hazards associated with the use of forced air warming in operating theatres*, JOURNAL OF HOSPITAL INFECTION., (2014) at Doc. 315, # 15.
[46] Ex. 1(David Rpt.) 31.
[47] *Id.* at 46.
[48] 3M is also critical of Dr. David for not including a literature review by ECRI in his report, but Dr. David reviewed the article when preparing his report in the *Walton* matter, and reviewed it again shortly prior to his MDL deposition. Ex. 3 at (310:18-312:25). Moreover, Dr. David noted that the ECRI article was extensively discussed in depositions in this case. *Id.* at (321:12-16) The article was inadvertently omitted from his reliance list.
[49] *Id.* at (303:2-4).

provided by an alternative design or accompanied by a warning.[50] Accordingly, the findings of the Kurz study are not relevant to his opinions.

In any case, these disputes about which studies the experts found important are matters for cross examination. ñAs a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility.ò *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir.1995). This is not a situation where an expert abjectly failed to familiarize himself with the relevant body of literature on the subject of his opinion, as was the case with 3Môs experts, including Jim Ho. Here, Dr. David performed a literature review consistent with and even more thorough than he would normally conduct when performing a device risk analysis outside litigation.

B. Dr. David's device examination was consistent with his usual practice in hazard analysis.

Before providing opinions about the Bair Huggerôs likely hazards, Dr. David wanted to personally acquaint himself with the device, perform an inspection, observe its operation, and disassemble its components. Dr. Davidôs examination of the device was limited to these purposes, as repeatedly testified. However, 3M attempts to use that testimony to suggest that Dr. Davidôs hazard analysis as a whole ñwas not to assess the Bair Hugger in the clinical context.ò[51] An examination of the cited testimony shows that Dr. David was referring to the purpose of his introductory device inspection:

> I wanted to see how the device is built, how itôs put together, where the components physically sit, where is the intake,

[50] Ex. 3, David Dep. (292:20-293:16).
[51] Doc. 766 at 16.

> where is the output, how you connect the blanket to it, and I did not seek to make any performance comparison or derive any clinical outcome of the device use.[52]

Ultimately, Dr. David relied on 3Môs own internal testing and documentation to establish the mechanical performance of the device. Dr. Davidôs device inspection was intended for personal assessment of its function and physical characteristics. Nonetheless, Defendants are critical of his choice to select a used device for the examination. However, Dr. David explained the reasoning behind this choice:

> My goal specifically was to see device operation and the inside of the device after it was used in the field. So on purpose, I wanted to get a device that had some field experience with ité Because it gives me a view of what the device's capability to sustain its features in the field after it's been used for a period of hours.[53]

For example, Dr. David discussed his examination of the feet of the device to determine its environment of use and placement as well as the examination of the filter housing and cavities within.[54] 3M is also critical that Dr. David examined the device ñwithout even knowing whether it was a properly functioning device,ò but in truth Dr. David determined it was not a properly functioning device, as it had several fault codes and did not appear to be operating at its normal performance level.[55] Dr. David observed that:

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[52] Ex. 3,David Dep. (27:10-18).
[53] *Id. at* (24:1-11).
[54] *Id. at* (24:12-20).
[55] Ex. 2, (David Rpt.) 10; 15.

> While this exemplar device was functional for my purposes -- which was to understand the basic operation and mechanisms of the device -- I was aware that in light of the deviceôs advanced age and presence of fault codes, this device may not be representative of the actual performance and tolerances of a properly functioning Bair Hugger unit in terms of airflow or heat delivery.[56]

Dr. David noted that ñ[w]hile this used exemplar device was in need of servicing and did not fully reflect the heating performance of a typical Bair Hugger unit, my examination was sufficient to familiarize myself with the operation of the device.ò [57]

C. Prior experience with the Bair Hugger is not necessary to perform a competent hazard analysis.

3M also asserts that Dr. Davidôs hazard assessment was flawed because he has never worked specifically with the Bair Hugger before this case, and he has ñnever researched, published or presented on the Bair Hugger system.ò[58] According to 3M, experts should not be allowed to testify about the device unless they have ñspecial knowledge or expertise related to the Bair Hugger system.ò[59] However, the fact that Dr. David has never worked specifically with the Bair Hugger does not disqualify him as an expert. Rather it is fully consistent with methodology outside of litigation. For decades, Dr. Davidôs job was to make himself familiar with the design, mechanical function, and potential patient risk of new medical devices, including and most especially devices with which he had no previous experience.

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[56] *Id. at* 10.
[57] *Id. at* 15.
[58] Doc. 766, p. 6.
[59] *Id.* at p. 19.

Moreover, Dr. Davidôs experience in the field of patient warming is vast. At the Texas Medical Center, Dr. David has directly overseen hospital practices with regard to patient warming.[60] In addition, ñfor over 30 years [he] was involved in reviewing warming devices for adult and pediatric patients.ò[61] These devices included the full array of warming modalities, whether ña literally oven-warmed blanket or devices which use fluids to warm patients or cool them or radiation-based devices that they are used in different environments.ò[62] In particular, Dr. David ñbecame intimately familiar with the issue of maintaining or warming patients under trauma situations.ò[63] Dr. David also performed several studies and published multiple research papers on pediatric ñforced warm airò devices known as Isolettes.[64]

Dr. David also published multiple studies on patient warming devices and clinical outcomes in cardiovascular surgeries at St Lukeôs Episcopal Hospital, home of the Texas Heart Institute, including study of heater-cooler devices.[65] Dr. David was part of the team that investigated and determined a new cleaning protocol for heater-cooler units.[66] Dr. David also has experience in studying the influence of air exchanges in the surgical theater, as well as experience reviewing and evaluating operating room pollution from

[60] Ex. 3 (David Dep.) (202:19-23).
[61] *Id. at* (203:6-10).
[62] *Id. at* (203:10-14).
[63] *Id. at* (204:7-9).
[64] *Id. at* (204:10-205:7).
[65] *Id. at* (209:10-210:23).
[66] *Id. at* (216:12-217:5).

anesthesia-based gases.[67] In short, Dr. David is eminently familiar with patient warming modalities as well as ñthe proper design and implementation of studies to determine the existence, nature and magnitude of potential risks and benefits associated with various device designs and the extent to which those risks and benefits are realized in clinical practice.ò *Taylor*, 1999 WL 310647 at *4.

D. Dr. David Applied a Reliable Hazard Analysis Methodology

3M complains (at 18) that Dr. Davidôs risk assessment methodology is ñunreliableò because he does not rigidly follow the protocol of a single particular risk management standard. Rather, Dr. David has adapted his own hazard analysis process from his decades of experience, integrating elements from a broad base of industry standards and guidelines. As Dr. David stated in his report, ñmy work has provided me with decades of experience in the methodologies of hazard analysis and risk assessment.ò[68] One of the cited sources of Dr. Davidôs methodology is the risk evaluation system published by MITRE, in which ñ[h]azard analysis and risk management can be conceptualized as four distinct steps.ò[69] These steps are:

> 1. *Risk Identification:* Risk events and their relationships are defined.
>
> 2. *Risk Impact Assessment*: Consequences of risk events are assessed.
>
> 3. *Risk Prioritization Analysis*: Analytic rules applied to order identified events from most to least critical.

[67] *Id. at* (213:24-214:5).
[68] Ex. 1 (David Rpt.) 5.
[69] *Id. at* 6.

> 4. *Risk Mitigation*: Risks are mitigating by adequate planning, implementation, and progress monitoring.

3M criticizes this source -- used by Dr. David to define risk analysis -- because the MITRE guidelines for risk analysis were created for ñthe evaluation of a system, not a medical device.ò[70] Instead, 3M believes that Dr. David should have relied on a standard known as ISO 14971.[71] Although Dr. Davidôs education and background includes familiarity with ISO 14971, 3M complains he did not specifically consult that standard or base his report on it.[72] As Dr. David testified with respect to ISO 14971, he understands ñwhat the standardôs purpose and what the principle of the categories that it addresses, and how one will use it as contrast with other risk assessment programs.ò[73] However, ISO 14971 sets forth a protocol for manufacturers to follow when creating and monitoring a device, including guidelines for personnel supervision, record keeping, and management planning. Much of ISO 14971 would be irrelevant to Dr. Davidôs task and inquiry in this case. However, Section 4 of the standard, entitled ñPerform a Risk Analysis for Each Medical Device,ò lists steps which include:

- The identification of intended use and device characteristics
- The identification of hazards which could potentially affect safety
- Estimate the risk for each hazardous situation
- Reduce risk whenever risk is unacceptable

[70] Doc. 766, p. 16.
[71] *Id.*
[72] *Id.*
[73] Ex. 3, David Dep. (173:2-6).

These steps are fundamentally identical to those listed in Dr. Davidôs methodology and used in hazard analysis methodologies worldwide. Dr. Davidôs report describes how this methodology is applied:

> When evaluating medical devices for patient risk, the investigator starts by understanding the deviceôs function, operation, and environment of use. This includes an examination of the device, as well as an analysis of how its performance may impact the patient, the health care staff, and the overall environment. The investigator also considers the relative safety of alternative technologies. An investigation into the potential risk of a device is also aided by the investigatorôs professional experience, a review of related published research, and evaluations by other qualified experts. To the extent possible, it also helpful to acquire information directly from the manufacturer of the device. The manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information é In this case, I have been provided access to confidential internal documents relating to the device and its development, rather than solely relying on publicly available information.[74]

3M complains that in performing his risk assessment, Dr. David did not properly consider the clinical benefits conferred by the Bair Hugger in the form of normothermia.[75] However, Dr. David made it clear that his risk assessment contemplated the use of alternative devices to maintain normothermia:

> Q. Dr. David, you were asked some questions about risk-benefit. Do you remember those questions?
>
> A. I do.

[74] Ex. 1 (David Rpt.) 6-7.
[75] Doc. 766 at 20.

> Q. First of all, is it your opinion that the Bair Hugger should be taken out of rooms and not replaced with any form of patient warming?
>
> A. No.
>
> Q. Are there other devices available, other design concepts which are feasible to be made without the same risk mechanism that you identified in your report?
>
> A. Right. I indicated in my report and so is my opinion that I identify specific products with different features that remove the risk introduced by the Bair Hugger 750 and yet serve the purpose of controlling patient temperature environment.[76]

Finally, 3M claims that Dr. David did not review enough documents in his hazard analysis, and attempts to compare the volume of materials reviewed by Dr. David with the materials reviewed by their own expert Tim Ulatowski.[77] However, not only did Mr. Ulatowski review large amounts of irrelevant materials, but his collection of documents omitted the materials most critical to his opinion -- the decision-making documents for the 510(k) clearance for marketing the Bair Hugger for use in the operating room.[78] The old adage of quality over quantity rings true here. Dr. David ñrequested specific documents or informationò in addition to the testimony and exhibits he reviewed, the literature he located, and the reference materials he assembled.[79] Dr. David explained that the level of information available to him exceeded that which he usually reviews when performing the same task outside litigation:

[76] Ex. 3, David Dep. (292:20-293:16).
[77] Doc. 766 at 4.
[78] *See* Doc. 755 (Motion to Exclude Ulatowski), p. 6-10
[79] Ex. 3, David Dep. (307:21-24).

> In coming to my opinions in this case, I had the unique benefit of reviewing internal confidential documents generated by the Defendant concerning the issue of airborne contamination from the use of the Bair Hugger. When I am conducting a hazard analysis of a medical device outside of the litigation setting, I do not typically have access to these kinds of materials when forming opinions about the risk of a product. The internal documents of a company help provide a more complete picture of the device itself, the research conducted on the device, and information which would otherwise be withheld from the public.[80]

During his deposition, Dr. David testified that ñIôm comfortable that I received the material that I need to arrive at the opinions.ò[81]

E. Dr. David is Qualified to Discuss Filtration Applications in Medical Devices.

3M next criticizes Dr. David because he is not a specialized expert in filter technology.[82] However, Dr. David has worked specifically in the field of filtration on medical devices, including the implementation of filters in mechanical ventilators and bedside monitors.[83] Dr. David has been consulted by device manufacturers regarding the ñprotection of the device from penetration of bacteria from the outside as well as protection of the device from developing pathogens in the internal cavities.ò[84] For example, Dr. David travelled to Germany to consult for Dräger Medical developing a new pediatric ventilator, including ñhow the device is going to be maintained, its

[80] Ex. 1 (David Rpt.) 31-32.
[81] Ex. 3, David Dep. (307:21-24).
[82] Doc. 766 at 20.
[83] Ex. 3, David Dep. (231:17-24).
[84] *Id.* at (231:24-232:4).

cleanliness, in face of some challenging environments, challenging in regard to pathogens.ò[85]

While it is true that Dr. David did not conduct any filter testing, such testing was unnecessary because the filters at issue have been extensively tested, both internally at 3M and in the published literature. Dr. Davidôs statements about the Bair Hugger in his report are based on 3Môs own internal testing of filter efficiency as well as 3Môs own statements and admissions about its performance. *See, e.g., In re Mentor Corp. ObTape*, 711 F.Supp.2d at 1368 (ñAs to Mentorôs internal documentsé the Court finds that those items may be relied upon by Plaintiffsô experts in reaching their opinions.ò) (*citing United States v. Steed,* 548 F.3d 961, 975 (11th Cir. 2008) (per curiam) (noting that experts may rely on information of a type reasonably relied upon by experts in the field)).

Additionally, while Dr. David has examined a Model 750 filter, 3M criticizes the fact that ñhe has never even seen the 500 Series filter in person.ò[86] This argument is highly disingenuous. Dr. Davidôs report describes the difference between the Model 500 series high-efficiency filter and the Model 700 series lowered-efficiency filter, and it explicitly discusses the fact that the original Model 500 series high-efficiency filter has not been manufactured for nearly ten years. Dr. David explained that [redacted]

[85] Ex. 3, David Dep. (232:20-23).
[86] Doc. 766, p. 22.

[redacted][87] As such, it was impossible for Dr. David to examine the original filter personally. Even if the original 500 series filter had been available, choosing not to examine it personally is a matter for cross-examination, not exclusion.

V. Dr. David has a Reliable Basis to Testify About Safer Alternative Designs.

Dr. David endorses three potential classes of alternative designs:

- Electric resistive mattress designs
- Closed recirculating forced air designs
- Conventional forced air designs with mitigations and warnings[88]

3M baselessly argues that Dr. Davidôs opinions on safer alternative designs should be excluded.[89] Dr. David has a valid basis in biomedical engineering to conclude that his proposed alternatives are safer while providing the same clinical goal.

A. Electric Resistive Mattress Designs

As Dr. David explained, ñ[w]hile the Bair Hugger uses airflow through a blanket to provide both conductive and convective heat, a similar result can be achieved using an electric heating mattress design to provide primarily conductive heat without convection.ò[90] Dr. David noted that conductive heating sources have been shown to be ñequal efficiency to the Bair Hugger forced-air blanket in maintaining temperature.ò[91] Dr.

[87] Ex. 1, (David Rpt.) 25.
[88] *Id.*
[89] Doc. 766 at 23.
[90] Ex. 1 (David Rpt.) 38.
[91] Ex. 3, David Dep. (295:3-5).

David identifies one such commercially available example, the VitaHEAT UB3 device distributed by 3M.[92]

Although this Court previously concluded that an electric blanket design was too conceptually different from the Bair Hugger, finding that ñ[t]he Bair Hugger system could not be modified to become a conductive patient warming device,ò[93] Plaintiffs respectfully continue to believe that the courtôs ruling adopts an impermissibly narrow approach to the doctrine of a safer alternative design, dooming from the outset all design defect cases in which the product requires drastic design changes to achieve its purpose safely. Moreover, this Courtôs finding that the VitaHEAT UB3 and the Bair Hugger are ñsubstantially different productsò runs headlong into the ñsubstantial equivalenceò doctrine recognized by other courts. *See, e.g., Cerner Corp. v. Visicu,* 2011 WL 27577, at *7 (W.D. Mo. 2011) (ñAn FDA decision that a device is substantially equivalent to a predicate device . . . means that they have a *similar category of technological characteristics.*ò)(emphasis added).

In identifying a resistive mattress warming devices as a safer alternative design, Dr. Davidôs report describes the process of alternative design for a medical device. Dr. explained that implementation of a safer design could involve the simple addition or removal of components. However, he explained that:

> In still other cases, a safer alternative design solution will require that components of the device be fundamentally re-engineered. In doing so, the re-engineering process can

[92] Ex. 1 (David Rpt) at 38.
[93] Doc. 249, p. 3.

> incorporate alternative technology if that technology can achieve the same device design goals in a safer way. The re-engineered device should be able to function in the same clinical environment and fulfill the same clinical purpose. If the re-engineered device performs a different clinical function or if it is inappropriate in the same clinical role, then the engineer has created a substantially different kind of product and not an alternative design.[94]

As such, Dr. David has concluded that electrical resistive mattress designs such as the VitaHEAT UB3 are safer alternative patient warming designs which provide the same clinical benefit. Ultimately, any dispute other whether such a device constitutes an alternative design should be decided at trial. *Kimball v. R.J. Reynolds Tobacco Co.,* 2006 WL 1148506, at *3 (W.D. Wash. 2006) (declaring that ñthe jury must decideò whether a product is an alternative design).

B. Closed Re-Circulating Forced Air Designs

Dr. David also concluded that a modified forced air design, in which the system is self-contained and recirculates with no exhaust, could provide the same heating benefit without disturbing operating room air. One product using this concept is the Tablegard device, created by Berchtold Surgical. ñLike the Bair Hugger, the Tablegard system uses forced air through a blower, providing heated air to combat perioperative hypothermia. However, the Tablegard system uses a closed recirculation system.ò[95] According to FDA

[94] Ex. 1 (David Rpt.) 38.
[95] *Id.* at 39.

filings, the device features ña connectable and thermally regulated warm air blower unit,ò which is then blown through a hose into a ñvinyl and polyurethane cover.ò[96]

Above: Tablegard blower and hose.

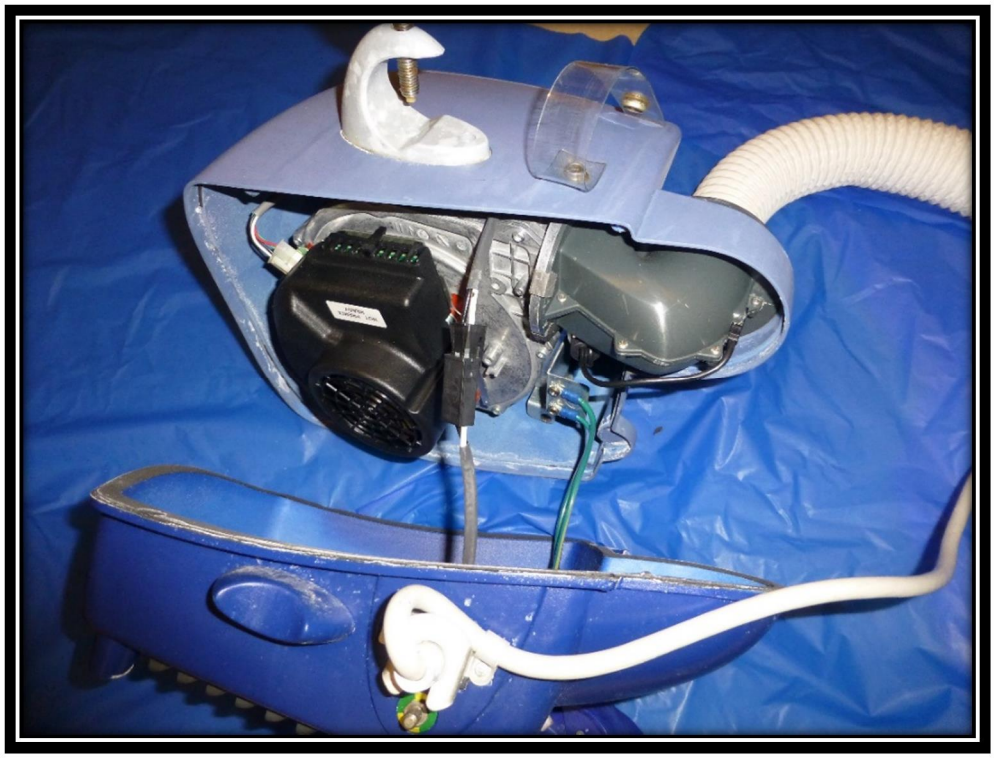
Unlike the Bair Hugger cover, which exhausts its air into the operating room after directly contacting the patient, the Tablegard system is ñfitted with air inlet and outlet ports to receive and recirculate warmed air.ò[97] As a result, the design of the Tablegard device has been able to use the mechanical concept of forced-air warming to provide contamination-free conductive heating. As Dr. David concluded, ñ[o]ne alternative design is to modify the method by which the device transfers heat to the patient.ò[98] Dr. David concluded, ñ[t]he design goals of this concept would address both of the mechanisms of risk posed by the Bair Hugger ï air circulation and internal

[96] Ex. 4 (Tablegard 510k Summary) p. 1.
[97] Ex. 4 (Tablegard 510k Summary) p. 1.
[98] Ex. 1 (David Rpt.) 38.

contamination.ò[99] As Dr. David explained in deposition, ñitôs a closed loop, [so] I donôt think that you need to be an expert to realize that youôre removing a threat. You therefore are reducing exposure to the risk.ò[100]

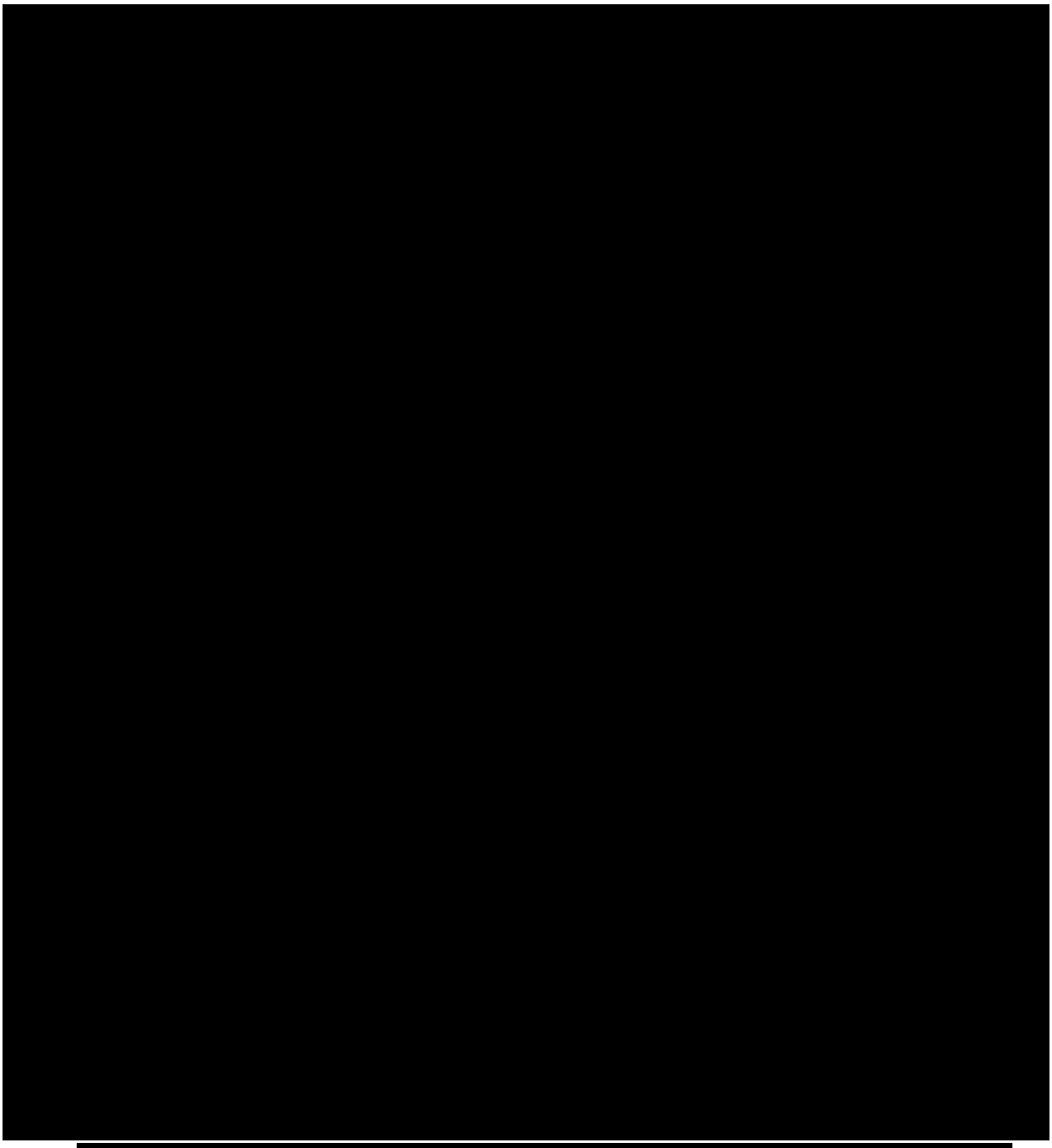
3M argues this evidence should be excluded because the Tablegard device uses ñconductive heating technology.ò[101] However, the key question is not how the heat ultimately travels to the patient. Rather, as this Court held in its discovery order on this issue, the key question is whether the Bair Hugger system ñcould be modified to becomeò something like the Tablegard re-circulating system.[102] This answer to this question is undoubtedly yes. As noted in FDA 510(k) filings, ñ[t]he differences between the Tablegard Pressure Relieving Patient Warming Mattress and the [Bair Hugger] are minimal.ò[103] And as Dr. David explained, ñthe [Bair Hugger] device is relatively simple in construction. The enclosure contains the following major components: blower, heating element, electronic controller, temperature sensors, mechanical hose adapter, and user control panel.ò

[99] *Id.*
[100] Ex. 3, David Dep. (291:4-7).
[101] Doc. 766, at 25.
[102] Doc. 249, at 3.
[103] Ex. 4 (Tablegard 510k Summary) p. 2.



The Tablegard device includes the same components. Both units feature a blower and heating element in an enclosure, attached to a hose which delivers heated air to an inflating receptacle positioned along the surgical table. The chief difference is that the Tablegard uses a closed system which does not exhaust air in the operating room, while placing the patient on the inflatableôs surface.[104] The air is then re-directed back into the device, at the same corresponding location of the Bair Huggerôs current air inlet. In fact, 3M engineers investigated the concept of [redacted].[105]

[104] Ex. 4 (Tablegard 510k Summary) p. 2.
[105] Ex. 1 (David Rpt.) 37.



ña competitorôs contemporaneous use of the proposed design alternative for the same purpose in the same consumer market is sufficient evidence to establish a genuine issue of fact as to the existence of a feasible design alternative.ò *Standard Fire Ins. Co. v. Broan Nutone, LLC,* 2008 WL 5560882, at *6 (S.D.Miss. July 1, 2008). Dr. David

confirmed that the Tablegard accomplishes the same purpose in the same consumer market, stating that ñ[l]ike the Bair Hugger, the Tablegard system ós intended for use on operating tables, surgical and diagnostic surfaces in hospitals or surgical centers to prevent and treat hypothermia.ôò[106] Based on his review of the evidence, Dr. David concluded ñthat the design concept used by the Tablegard system is more likely than not safer and as effective as the Bair Hugger.ò[107]

C. Conventional Forced Air Devices with Mitigations and Warnings

The final type of alternative design proposed by Dr. David are conventional forced air warming devices which include mitigations in their design or warnings to the user. For example, Dr. David believes that ñwhile far from optimal, devices with HEPA filters and/or antimicrobial technologies would have been a safer alternative.ò[108] Dr. David explained that ñwhile the use of a forced-air warming device still poses a risk due to disruption of the sterile surgical field and introduction of airborne particles to the wound, a HEPA filter would help mitigate some of the risk by preventing the warming unit from collecting and incubating bacteria of its own.ò[109] Dr. Davidôs report includes literature regarding the effectiveness of silver ion antimicrobials, as well as testing produced by 3M showing [redacted]. With respect to Dr. Davidôs recommendation for a HEPA filter, he explained as follows:

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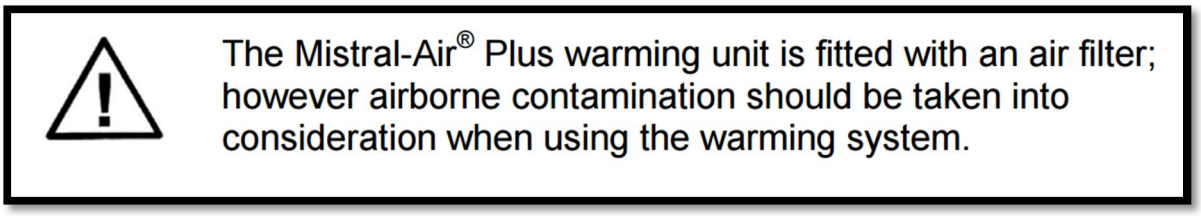
[106] Ex. 1 (David Rpt.) 39.
[107] *Id.* at 40.
[108] *Id.*
[109] *Id.*

> At the incident with the literature review that I cited in my report, looking at all the studies, the conclusion was simple that a HEPA filter is one of the ways to mitigate infection. The CDC article that I have in my publication also talks about filtering level efficiency. The literature from orthopedics, Bone & Joint Journal, is talking about one of the solution is increase filter efficiency. So there's ample evidence out there that there is a relationship between filter efficiency and the potential risk of infection at the surgical site.[110]

3M disputes Dr. Davidôs opinion that a HEPA filter would likely reduce infection risk from the Bair Hugger. 3M cites a recent study of infection rates between the use of the Bair Hugger and the competing Mistral warming device, which features a HEPA filter. The study found similar infection rates. However, this study is ultimately a comparison of apples and oranges when it comes to the choice of filter on the Bair Hugger. The study doesnôt measure Mistral infection rates using lowered filtration similar to Bair Hugger, nor does it measure Bair Hugger infections rates with increased filtration. Given the differences between the devices, and the other mechanisms of infection at play, this study is not useful at assessing the filtration adequacy of the Bair Hugger.

Irrespective of its performance, the Mistral features another notable difference from the Bair Hugger in the form of a conspicuous warning to clinical consumers. Dr. Davidôs report discusses the specific warning about the potential for airborne contamination in the Service Manual of the Mistral-Air system.[111]

[110] Ex. 3, David Dep. (263:8-21).
[111] Ex. 1 (David Rpt.) p. 41.



Dr. David explained that:

> This warning is especially relevant to orthopedic procedures, which are conducted under rigorous clean conditions. The warning appears in the Safety Precautions section of the manual. Also, the warning is accompanied by a symbol, in this instance an exclamation mark, which is a familiar measure to draw the userôs attention to the urgency of the warning. These kinds of warnings are reviewed by biomedical engineers when selecting and placing hospital equipment. If the Bair Hugger had included this kind of warning, for example, its clinical customers could have scrutinized the Bair Huggerôs effect on operating room airflow and been in a better position to make the decision to curtail the use of the device in high-risk orthopedic implant procedures.[112]

Dr. David further explained that ñ[t]here are no warnings for the 500 or 700 series Bair Hugger devices regarding the potential for airborne contamination,ò and that 3Môs corporate representative testified these warnings were omitted ñdespite the fact that the risk of airborne contamination was in fact known to the company at that time.ò[113] The older Model 200 series, which was not intended for use in the operating room, included a warning regarding the potential for airborne contamination.[114] Dr. David thus opined

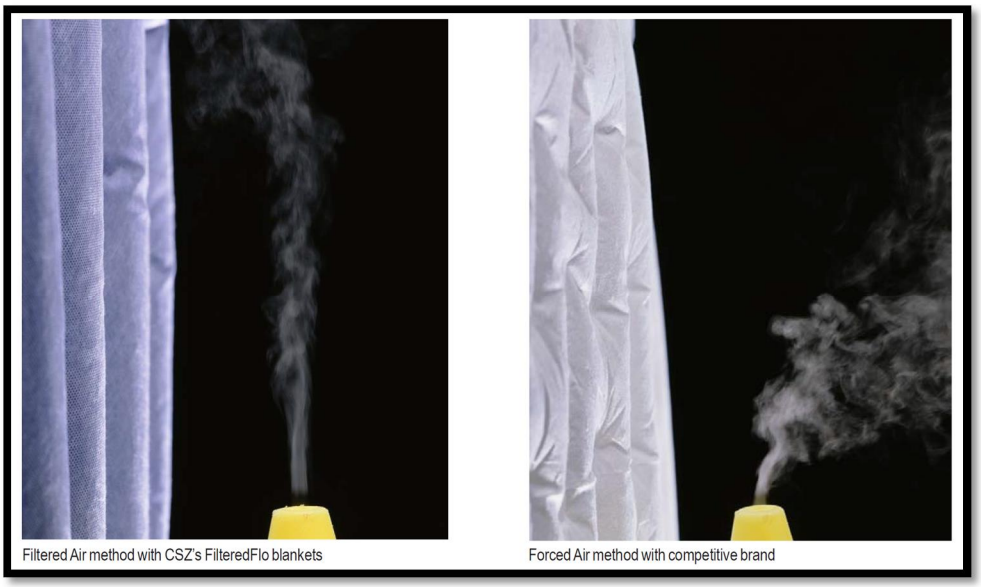
[112] Ex. 1 (David Rpt.) 41.
[113] *Id.*
[114] *Id.*

ñthat the removal of an airborne contamination warning from the Bair Hugger makes the device unreasonably dangerous.ò[115]

Finally, Dr. David also discussed designs differences in the WarmAir warming device, manufactured by Cincinnati Subzero, a product largely ignored in 3Môs Motion. Dr. David explained the design concepts in the WarmAir device intended to mitigate the disruption of theater airflow:

> There are other air-based warming products which are designed with the intention of reducing the disruption of theater ventilation or the potential for contamination. For example, the WarmAir device, manufactured by Cincinnati Sub Zero, is marketed with a ñFilteredFlo blanketò which features a ñnon-woven delivery surface.ò These blankets require ñno perforation,ò which is designed to avoid ñunwanted and potentially dangerous particles in your operating room.ò The manufacturer states that the blanket design also ñpermits use of a lower velocity blower to supply gently moving, clean airò which ñminimizes air currents that may spread contaminants to your patient.ò Published literature shows that the WarmAir device produces significantly less airflow than the Bair Hugger but was equally effective in maintaining perioperative normothermia in patients undergoing major abdominal and orthopedic surgery.[116]

[115] Ex. 1 (David Rpt.) 41.
[116] *Id* at 42.



Dr. David stated that ñit is my opinion that the design concepts and goals pursued [in the WarmAir device] could be feasibly integrated into a patient warming device that would help address and mitigate the risk of airborne contamination.ò[117] For each of the proposed alternatives that Dr. David discussed, he employed the same methodology he would use outside litigation for selecting a device to mitigate a risk factor. Dr. Davidôs extensive background in biomedical engineering, along with his review of evidence and literature relating to the mechanical principles of the hazard, provides a valid basis for his conclusions about the potential of these design concepts and label changes to reduce patient risk.

CONCLUSION

This Courtôs only role under *Daubert* is to determine if ñan expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the

[117] *Id.*

same level of intellectual rigor that characterizes the practice of an expert in the relevant field.ôö *Hollander*, 289 F.3d at 1206 (quoting *Kumho Tire,* 526 U.S. at 152). Here, Dr. David is one of the most impressively credentialed biomedical engineers in the nation, and he has applied his decades of experience in adverse event investigation and medical device hazard analysis. He has applied the same methodologies he employs outside litigation, to even a greater level of rigor normally afforded in the hospital, regulatory, or industry environment. 3Môs complaints about his testimony are properly addressed through cross-examination, and therefore 3Môs Motion should be denied.

Respectfully submitted,

Dated: October 3, 2017

CIRESI CONLIN L.L.P.

/s/Michael V. Ciresi_____
Michael V. Ciresi (MN #0016949)
Jan M. Conlin (MN #0192697)
Michael Sacchet (MN # 395817)
Ciresi Conlin LLP
225 S. 6th St., Suite 4600
Minneapolis, MN 55402
Phone: 612.361.8202
Email: MVC@CiresiConlin.com
JMC@CiresiConlin.com
MAS@ciresiconlin.com

MESHBESHER & SPENCE LTD.

/s/ Genevieve M. Zimmerman
Genevieve M. Zimmerman (MN #330292)
1616 Park Avenue South
Minneapolis, MN 55404
Phone: (612) 339-9121
Fax: (612) 339-9188
Email: gzimmerman@meshbesher.com

LEVIN PAPANTONIO, P.A.

/s/ Ben W. Gordon, Jr.
Ben W. Gordon (FL # 882836) ï *Pro Hac Vice*
J. Michael Papantonio (FL # 335924)
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996

FARRAR & BALL, LLP

s/ Mark D. Bankston
Mark D. Bankston (TX # 24071066)
1010 Lamar, Suite 1600
Houston, Texas 77002
(713) 221-8300 Telephone

Phone: (850) 435-7090
Fax: (850) 436-6090
Email: bgordon@levinlaw.com

(713) 221-8301 Fax
Email: mark@fbtrial.com

Plaintiffs Co-Lead Counsel